REMARKS/ARGUMENTS

Claims 1-55 are pending herein, claims 1, 22, 24, 31, 40, 43, 49 and 55 being independent. Claims 1, 22, 24, 31, 40, 49, 52 and 55 have been amended. No new matter has been added.

The Examiner has rejected claims 1, 6, 7, 9, 13, 16-18, 21, 23-26, 28, 31-34, 36, 39-41, 49 and 51 under 35 U.S.C. § 102(b) as anticipated by United States Patent No. 6,336,916 (Bormann, *et al.*); claims 2-5, 43-48, 50 and 52-55 under 35 U.S.C. § 103(a) as obvious over Bormann, *et al.*, in view of United States Patent No. 4,571,244 (Knighton); claims 8, 10, 15, 19, 20, 30, 35, 38 and 42 under 35 U.S.C. § 103(a) as obvious over Bormann, *et al.*; claims 11, 12, 14, 27, 29 and 37 under 35 U.S.C. § 103(a) as obvious over Bormann, *et al.* in view of United States Patent No. 6,833,488 (Bucevschi, *et al.*); and claim 22 under 35 U.S.C. § 103(a) as obvious over Bormann, *et al.* in view of United States Patent No. 4,465,479 (Meisch).

Applicants have carefully considered the Examiner's rejections, and the reasons offered in support thereof. For the reasons set forth in detail below, withdrawal of the rejections is believed appropriate.

The following summary of the invention is offered for the benefit of the Examiner and is taken from the specification. It is not intended to argue limitations not present in the claims, or to argue for the interpretation of any claim term that is different from, or more narrow than, the broadest interpretation of such term as would be understood by one of ordinary skill in the art upon a full and fair reading of the specification.

The invention is directed to a system and method for delivering a solution to a patient through a self-priming intravenous (IV) delivery system, together with components and sub-assemblies of such systems and methods of using such systems. The relevant component of such systems is a drip chamber which holds the solution after being drawn from a container in which the

solution is stored before the solution is delivered to the patient through a conduit. As is known, the drip chamber acts as a holding area, where the delivery speed of the solution can be visually monitored by a dispensing professional, such as a nurse. Since the speed at which the solution is dispensed to the patient is always a matter of concern, it is imperative that the speed of the flow of the solution through the system be monitored. For this reason, drip chambers are usually substantially transparent, to permit the monitoring of the drip flow.

Furthermore, since the drip chamber generally starts empty, it must be allowed to fill up to a desired level ("primed") and to allow any air in the system to be removed before solution is dispensed to the patient. In many prior art systems, the drip chambers are made of a resilient material, to allow for manual priming, by, for example, squeezing the drip chamber to force air out of the drip chamber, and then allowing the drip chamber to revert to its original shape, thereby drawing the solution into the drip chamber at a faster rate until a desired level of solution is obtained in the drip chamber. This, however, allows the "over-priming" of the drip chamber, so that the distance between the top of the drip chamber to the top of the reservoir of solution in the drip chamber may be too small, rendering it difficult to monitor the rate of the drip flow. Over priming is to be avoided.

This is remedied in the inventive system by the provision of the claimed opening in the side wall, which opening is set at a level on the side wall that is at the level of solution that provides the desired level of solution in the drip chamber. The opening is covered by the claimed vent plug, which seals the opening when the level of solution reaches the vent plug (in the opening), and provides *self-priming* of the system, *i.e.*, without intervention by the user. The opening is oriented in a direction transverse to the flow of the drops of solution in the drip chamber so that the transparent side wall is open to view from all sides and the rate of flow of the drops of solution may,

therefore, be monitored without obstruction. This feature of the invention is nowhere shown in the art, and would not be an obvious modification of the art applied by the Examiner.

The primary reference applied by the Examiner is Bormann, *et al.* which teaches what the inventors thereof believed to be the best solution to the same problems addressed by applicants: allowing the user to monitor the flow rate of the solution being administered (*see*, col. 1, lines 31-33) and self-priming of the drip chamber without worry of over priming (*see*, col. 1, lines 61-67). The structure of the device taught by Bormann, *et al.* is quite different, however, from that of the invention claimed herein and has drawbacks.

The Examiner applies Bormann, *et al.* as allegedly showing the claimed opening and vent plug (Office Action, p. 2, para. 1).. However, the element of Bormann, *et al.* that the Examiner likens to the claimed vent plug -- porous medium 10 -- is disposed in a position oriented *parallel* to the flow of drops in the drip chamber, so as to allow gas to exit the drip chamber through a gas passageway 5 (see Fig. 1). This orientation is perpendicular to that now claimed for the opening and vent plug in the instant invention. E*ven though Bormann,* et al. *expressly teach that the ability to observe the rate of flow is important* (*see*, col. 1, lines 52-54), the positioning of gas passageway 5 in Bormann, *et al. obscures* the flow of drops through the drip chamber from certain vantages (for example from the right in the Figures of Bormann, *et al.*), limiting the range of view of the flow of drops of solution in the drip chamber.

The obstruction of the view of the flow rate is avoided in the claimed system by orienting the opening in the side wall in a direction transverse to the flow of the drops which is out of the sightline of the user who needs to observe the flow of drops in the drip chamber from any angle. One of ordinary skill in the art would not see any teaching or suggestion in Bormann, *et al.*, or the other applied references, to re-orient the porous material thereof to avoid the use of the long vertical

gas passageway **5**, which therefore teaches away from the structure claimed. M.P.E.P. § 2141.02 (VI) ("A prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention." – emphasis in original).

When the teachings of Bormann, *et al.* are taken as a whole, as one must, those teachings show that the opening in the drip chamber which allows gas to escape therethrough *must* be oriented *parallel* to the drip flow, because no other solution is offered by Bormann, *et al.* Accordingly, the invention as claimed is distinct from that taught by Bormann, *et al.* Thus, Borman et al. does not anticipate the invention as claimed, nor does it render the claimed invention obvious. This is not surprising, since Bormann, et al. are concerned primarily with the drip chamber as an independent element, while aspects of the invention herein are directed to the system *as a whole,* which provides the benefits of self-priming.

As to the system of claims 43-48, Bormann, *et al.* fail to teach the use of a wettable, sealable, vent plug material to permit the automatic priming of the patient conduit line, a shortcoming acknowledged by the Examiner in the comparison of the gas debubbler of Knighton to the termination end cap vent (*see, e.g.*, Office Action, page 6). This is inapposite, however, since Knighton teaches the use of a double-ended chamber with different filters on the two ends. On the one end is a filter 28 that allows gas to pass therethrough but not liquid and at the other end is a filter 26 that allows liquid to pass therethrough but not gas. With this arrangement, gas in the liquid to be conveyed through the debubbler becomes trapped behind filter 26 and expelled through filter 28, and therefore does not reach the patient. However, Knighton does not teach the use of a wettable, sealing vent plug to allow for self-priming, since the two filters 26 and 28 are never sealed. It would not be obvious to one of ordinary skill in the art to modify the filters of Knighton to make one of them sealable by wetting; since that would close the end of that

Knighton teaches should be open. Making this substitution, therefore, flies directly in the face of Knighton's teachings, and would not be an obvious modification thereof, as suggested by the Examiner.

Thus, the combination of Bormann, *et al.* and Knighton could not result in the invention as claimed herein.

The additional references applied by the Examiner do not overcome these drawbacks, and therefore overcome none of the deficiencies of the primary combination.

It is submitted, therefore, that the invention as claimed is patentably distinct from the references applied by the Examiner, taken alone or in any combination. Withdrawal of the rejections, and the allowance of the application are, therefore, respectfully solicited.

It is believed that no fees or charges are required at this time in connection with the present application. However, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
COHEN PONTANI LIEBERMAN & PAVANE LLP

By _____

Edward M. Weisz
Reg. No. 37,257
551 Fifth Avenue, Suite 1210
New York, New York 10176
(212) 687-2770

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